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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,435	02/22/2002	Mark G. Erlander	485772003300	8216

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,435	ERLANDER ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action and amendment filed on August 30, 2004 has been entered.

2. Claims 1-20 are pending. New claim 21 is added.

3. This application filed on February 22, 2002, claims benefit of US provisional 60/271,344 filed on February 22, 2001 and US provisional 60/314,697 filed on August 23, 2001.

Response to Arguments

4. Applicant's response to the office action is fully considered and is found persuasive.

5. With regard to the rejection made in the previous office action under 35 USC 112, second paragraph, Applicants amendment and arguments have been fully considered and rejection is withdrawn in view of the amendment.

6. With regard to the rejections made in the previous office action under 35 USC 102(a) and 102(b), Applicants amendment and arguments have been fully considered and rejections are moot in view of the amendment and new grounds of rejections.

New Grounds of Rejections

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 1-3, 6-11, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable Reiter et al. (Genes, Chromosomes & Cancer, Vol. 27, pp. 95-103, 2000) in view of Fend et al. (Am J Pathol., Vol. 154, No. 1, pp. 61-66, 1999).

Reiter et al. teach a method of claim 1, 19, for detecting the presence of a ligand (nucleic acid) in a prostate tissue sample comprising: (a) contacting said sample with a binding agent (anti-digoxigenin antibody) attached to a detectable nucleic acid molecule (digoxigenin labeled DNA probe) (see page 96, col. 2, paragraph 1-2, page 97, col.1, which indicates the detectably labeled DNA (digoxigenin labeled PSCA probe) is attached to a binding agent (anti-digoxigenin antibody)); staining said tissue sample to identify cells of interest (see page 96, col. 2, last line of paragraph 2, page 97, col. 1, line 1-2); (c) detecting said detectable nucleic acid (PSCA probe signal) as an indication of the presence of said ligand (see page 97, col. 1, paragraph 1-2).

With regard to claim 8, Reiter et al. teach plurality of agents (antibodies) are attached to a plurality of different nucleic acid molecules (PSCA, MYC probes) to detect simultaneously the plurality of ligands (PSCA and MYC specific ligands) (see page 96, col. 2, paragraph 2);

With regard to claim 2, 9, Reiter et al. teach that the binding agent is an antibody (see page 96, col. 2, paragraph 2);

With regard to claim 3, Reiter et al. teach that said sample comprises a tissue section (see page 96, col. 2, paragraph 1-2);

With regard to claim 6, Reiter et al. teach that said staining is by histochemical staining (see page 96, col. 2, last line of paragraph 2, page 97, col. 1, line 1-2);

With regard to claims 10-11, Reiter et al. teach that the sample is prostate tissue and the ligand is prostate specific ligand (see page 96, col. 1, paragraph 2, col. 2, paragraphs 1-2).

However, Reiter et al. did not teach capturing or isolating stained cells.

Fend et al. teach a method of claims 1,7, for detecting a ligand in a cell or tissue sample comprising staining the tissue sample using immunohistochemistry and capturing or isolating said cells of interest using laser capture microdissection (see page 62, col. 1, paragraphs 1-2, col. 2, paragraph 1). Fend et al. disclose that immunohistochemical staining technique for tissue sections, in combination with capturing cells by laser capture microdissection allows very fast, easy and precise isolation of specific cell populations for mRNA analysis (see page 62, col. 1, paragraph 1).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of detecting a ligand in a tissue or cell sample as taught by Reiter et al. with the step of capturing or isolating the cells of interest as taught by Fend et al. to achieve expected advantage of developing a sensitive and enhanced method for detecting a cell specific ligand because Fend et al. taught that immunohistochemical staining technique for tissue sections , in combination with capturing cells by laser capture microdissection allows very fast, easy and precise isolation of specific cell populations for mRNA analysis (see page 62, col. 1, paragraph 1). An ordinary practitioner would have been

motivated to combine the method of Reiter et al. with the incorporation of the step of capturing or isolating specific cells of interest as taught by Fend et al. to improve the sensitivity and specificity of the detection method because the skilled artisan would have a reasonable expectation of success that the inclusion of capturing or isolating cells of interest would result in isolating or capturing specific cell populations from a highly heterogeneous primary tissue, such as tumor samples, by eliminating unwanted cell populations which would facilitate further characterization of these specific cells.

B. Claims 1-2, 4-5, 13-15, 18-19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberwine (USPN. 5, 922, 553) in view of Fend et al. (Am J Pathol., Vol. 154, No. 1, pp. 61-66, 1999).

Eberwine et al. teach a method of claim 1, 19, for detecting the presence of a ligand (protein) in cell sample comprising: (a) contacting said sample with a binding agent (tau-1 protein antibody) attached to a detectable nucleic acid molecule (cDNA tag with T7 RNA polymerase promoter) (see col. 5, line 34-59) is attached to a binding agent (tau-1 antibody) (see col. 5, line 63-67, col. 6, line 1-6); (c) detecting said detectable nucleic acid as an indication of the presence of said ligand (see col. 6, line 35-59).

With regard to claim 2, 21, Eberwine et al. teach that the binding agent is a protein an antibody (see col. 5, line 63-67, col. 6, line 1-6);

With regard to claims 4-5, Eberwine et al. teach that said detecting comprises quantitative PCR and the quantitation of said ligand (see col. 6, line 35-52, col.5, line 9-24);

With regard to claims 13-15, 20, Eberwine et al. teach that said nucleic acid molecule comprises T7 promoter and detection comprises identifying transcription initiated from T7

promoter which include solid support (patch pipettes, microtiter-plates or beads) comprising cDNA sequences conjugated to an antibody (see col. 5, line 34-59, col.6, line 35-52, col. 4, line 5-36).

However, Eberwine et al. did not teach staining and capturing or isolating stained cells.

Fend et al. teach a method for detecting a ligand in a cell or tissue sample comprising Staining the tissue sample using immunohistochemistry and capturing or isolating said cells of interest using laser capture microdissection (see page 62, col. 1, paragraphs 1-2, col. 2, paragraph 1). Fend et al. disclose that immunohistochemical staining technique for tissue sections, in combination with capturing cells by laser capture microdissection allows very fast, easy and precise isolation of specific cell populations for mRNA analysis (see page 62, col. 1, paragraph 1).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of detecting a ligand in a tissue or cell sample as taught by Eberwine et al. with the step of capturing or isolating the cells of interest as taught by Fend et al. to achieve expected advantage of developing a sensitive and enhanced method for detecting a cell specific ligand because Fend et al. taught that immunohistochemical staining technique for tissue sections , in combination with capturing cells by laser capture microdissection allows very fast, easy and precise isolation of specific cell populations for mRNA analysis (see page 62, col. 1, paragraph 1). An ordinary practitioner would have been motivated to combine the method of Eberwine et al. with the incorporation of the step of capturing or isolating specific cells of interest as taught by Fend et al. to improve the sensitivity and specificity of the detection method because an ordinary person skill in the art would have a

reasonable expectation of success that the inclusion of the step of capturing or isolating cells of interest would result in obtaining specific cell populations from a highly heterogeneous primary tissue, such as tumor samples by eliminating unwanted cell populations, which would facilitate further characterization of these specific cells.

C. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiter et al. (Genes, Chromosomes & Cancer, Vol. 27, pp. 95-103, 2000) in view of Fend et al. (Am J Pathol., Vol. 154, No. 1, pp. 61-66, 1999) as applied to claims 1-3, 6-11, 19, 20 above, and further in view of Wang et al. (Biochem Biophys Res commm, Vol. 259, pp. 21-28, 1999).

Reiter et al. in view of Fend et al. teach a method for detecting a ligand in a tissue or cell sample.

Neither Reiter et al. nor Fend et al. teach that said plurality of ligands comprise two forms of a polypeptide and the two forms are the phosporylated and unphosphorylated forms of a polypeptide.

Wang et al. teach a method for screening ligands for treatment of prostate cancer, wherein Wang et al. teach that the androgen receptor ligands stimulate androgen receptor (AR) phosporylation, and AR phosphorylation and dephosphorylation may serve as a new molecular target for screening androgen antagonists for the treatment of prostate cancer (see page 27, col. 1, lines 1-12, page 21, abstract).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method of detecting a ligand in a tissue or cell sample as taught by Reiter et al. in view of Fend et al. with the method of screening for two forms of a ligand as taught Wang et al to improve the detection method for the purpose of

identifying the ligands that serve as drug targets for treating prostate cancer because Wang et al. explicitly taught the two forms of a polypeptide might serve as a molecular target in identifying ligands that are useful for prostate cancer treatment (see page 27, col. 1, lines 1-12, page 21, abstract). An ordinary practitioner would have been motivated to combine the method of Reiter et al. in view of Fend et al. with the two forms of a ligand to achieve an improved method of detecting ligands that are useful as drug targets because an ordinary person skill in the art would have a reasonable expectation of success that the inclusion of identifying two forms of a ligand with the detection method would result in differentiating and isolating specific ligand expressing cell populations from a complex tissue that can be used for the treatment of prostate cancer.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
December 16, 2004

Jehanne Sitton
JEHANNE SITTON
PRIMARY EXAMINER
12/17/04